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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,014	12/04/2001	Chen Xing Su	10209.276	6898

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KIRTON AND MCCONKIE
60 EAST SOUTH TEMPLE,
SUITE 1800
SALT LAKE CITY, UT 84111

EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/006,014	SU ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's response and affidavit under 37 C.F.R. § 1.131, both received on 09 March 2007.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 3-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 9, 10, 12, and 13 under 35 U.S.C. 103(a) as being unpatentable over Gidlund is maintained.

Response to Arguments

The applicant's arguments, received on 09 March 2007, have been considered, but are not found to be persuasive.

The applicant's arguments do not overcome the rejection under 35 U.S.C. 112, because it is still unclear how the portion of the instant specification cited by the applicant supports the recitation in the instant claims of administering processed *Morinda citrifolia* juice with each dose being less than 0.1 mL per kg of body weight of the patient. How such a claim limitation can be properly supported by and derived from the instant specification has not been made clear at any point in the prosecution of this case. As such, the rejection under 35 U.S.C. 112 will be maintained.

As stated in a previous Office Action, the applicant has attempted to distinguish the instant claims over the disclosure of the prior art by stating that the a patient having a mass of 70 kg would be administered 7 mL of liquid extract per day. However, a very simple unit conversion would show that 7 mL is equivalent to less than 0.25 fluid ounces. The applicant has simply decided to ignore this important calculation, since other claims, such as Claims 9 and 12, require the administration of 2 to 3 fluid ounces. This would mean that at the ratio of less than 0.1 mL per kg of body weight of a patient, that patient would have to have a body mass of at least 590 kg, well over half of a metric ton. Therefore, the limitation of processed *Morinda citrifolia* juice administered in a dose of less than 0.1 mL per kg of body weight of the patient appears to contradict the applicant's own claims.

As stated in the previous Office Action, it is clear then that the claim limitation of a daily dosage of less than 0.1 mL per kg of body weight of a patient, as introduced into the claims in the amendment of 25 November 2005, is merely nothing more than an attempt to maneuver around what has been taught by the prior art. This is evidenced by the fact that in the specification as originally filed, there is never any explicit mention of dosages expressed in the

units of mL per kg of body weight of the patient. However, the expression of dosages in such units is readily apparent in the Gidlund reference. In that reference, the lower end of the range of dosages is 0.1 mL per kg of body weight of the patient, as cited by the applicant in the seventh line on page 8 of the present response. There appears to be a strong indication that the recitation in Claim 1 of a dosage of less than 0.1 mL per kg of body weight of the patient was taken directly from the disclosure of the prior art, rather than from the what was properly enabled by the instant specification, and incorporated into the instant claims in a clumsy attempt to amend the claims around the explicit disclosure of the prior art.

Furthermore, the data provided by the applicant to address the present rejection of the claims under 35 U.S.C. § 112 does not readily show how that data provides proper support and justification to the recited limitation of the administration of processed *Morinda citrifolia* juice of a dose of less than 0.1 mL per kg of body weight of the patient. It begs the question of how that claim limitation is precisely derived from the data presented in the specification and cited by the applicant in the response. In fact, the data cited by the applicant in the response is merely a repetition of what has already been presented in this application. That much is clear. Again, what is not clear is how that data provides support to the claim limitation in question. Calculations that show how the disputed claim limitation is derived from the data in the instant disclosure would be immensely helpful.

The examiner considers the property of selective cyclooxygenase-2 inhibition to be implicit and inherent to the disclosure of the prior art. As the art has already shown guidance that the invention of the Gidlund reference is useful for treating various conditions of pain, such as menstrual cramps, arthritis, sprains, and injuries, the examiner considers such a disclosure to

be further guidance and evidence towards that rationale. The applicant is reminded that a composition known in the prior art does not become patentable upon the discovery of a new property. See MPEP § 2112. The burden remains on the applicant to show the unobvious difference between the instantly claimed invention and the prior art that would render patentability unto the instantly claimed invention.

Furthermore, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). The applicant has said that a 70 kg patient would be administered a minimum of 7 mL of *Morinda citrifolia* extract per day. From there, the applicant offers no further explanation. The limitation of a dosage ranging from between 2 to 3 ounces recited in the instant claims corresponds to a dosage ranging from approximately 59 mL to approximately 89 mL. For a 70 kg patient, this falls well within the range of 0.1 to 2 mL of *Morinda citrifolia* extract per kg of body weight of a patient as taught by Gidlund. Therefore, the applicant has not set forth a persuasive argument that the Gidlund patent teaches a dosage that is unsuitable for selective COX-2 inhibition. By the unit conversions as seen above between dosages as expressed in mL per kg of body weight, as disclosed by the prior art, and in fluid ounces as recited in Claims 9 and 12, it is the position of the examiner that the instant claimed methods are not patentably distinct above the prior art.

The affidavit filed on 09 March 2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Gidlund reference.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Gidlund reference. While conception is the mental part of the inventive

act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The defect of the submitted affidavit is that not one iota of evidence has been submitted to support the inventor's statements. The examiner wishes to point out that 37 C.F.R. § 1.131(b) states:

> The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained.

In this respect, the submitted affidavit is shown to be entirely inadequate. As such, the prior art rejection of record will be maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sjo

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER